REMARKS

By this response, Applicant has amended claim 33 and has canceled claim 23. Thus, Claims 1, 5, 6, 9-22, 27, 29-31, 33, 36, and 38-43 are pending in the application.

Applicant would like to take this opportunity to than Examiner Lucas for meeting with his representative on January 15, 2009. At the interview, applicant's representative discussed the possibility of performing studies, using animals, which would provide data which applicant would urge would demonstrate the unexpected and unobviousness nature of the currently claimed invention. Applicant was interested as to whether the Examiner would consider such studies, of the type being considered, relevant to the issue of obviousness in the present application. The Examiner acknowledged that such studies, adequately explained as to relevance would be considered when submitted. Applicant's representative also urged that while Ganguly states that the disclosed composition can be administered in slow release form, there is no suggestion of the benefit or that such a manner of administration would permit the use of lower dosages than are normally administered or the benefit of avoiding known side effects from current treatment methods and compositions. Applicant continues to investigate the possibility of studies which would generate and provide data for submission to the Examiner once the studies are completed.

In the most recent Office action, mailed October 22, 2008, the Examiner has rejected claims 33, 36, 38-42 under 35 U.S.C. 112, second paragraph as to the sufficiency of the enabling disclosure presented in support of the claimed invention. In addition, claims 1, 9-23, 27, 33, and 38-43 remain rejected under 35 U.S.C. 103 (a), as unpatentable over Ganguly (WO 2000/23455). Claims 5, 6, and 36 stand rejected under 35 U.S.C. 103 (a) as unpatentable over Ganguly taken in view of Wong (6120803). Claims 29-31 stand rejected under 35 U.S.C. 103 (a) as unpatentable over Ganguly and Wong taken in further view of Brass (6849524).

As noted, claim 33 has been amended and claim 23 has been canceled as set forth above.

Applicant addresses the grounds of objections and rejections as follows:

Grounds of Rejection:

Rejection under 35 USC 112, second paragraph paragraph:

Applicant has modified claim 33, on which claims 36 and 38-42, depend in the manner suggested by the Examiner. Thus, this ground of rejection is believed to have been overcome.

Thus, Applicant would, respectfully, request that the Examiner reconsiders this basis of rejection and withdraws the rejection of the presently pending claims under 35 U.S.C. 112, second paragraph.

Rejections under 35 USC 103 (a):

Rejection of claims 1, 9-22, 27, 33, and 38-43:

At pages 4-7 of the most recent Office action, the Examiner has maintained the rejection of claims 1, 9-22, 27, 33 and 38-43.

The Examiner has taken the position that Ganguly discloses the administration of interferon and ribavirin for viral infections, suggests the use of sustained release dosage forms and urges that: "it would have been obvious to those of ordinary skill in the art to have optimized the treatment for patients to arrive at dosages within the provided ranges."

However, Ganguly does not actually direct one skilled in this art to a low dose sustained release form of the ribavirin. As stated at page 39, line s13-15 of Ganguly, "For convenience, the total daily dosage may be divided and **administered in portions** during the day as required."(Emphasis added.) Similarly at page 43, lines 24-26 Ganguly states: " A typical recommended daily dosage regiment for oral administration can range from about 1 mg/kg/day to 100mg/kg/day **in two to four divided doses**." (Emphasis added.) Thus, when Ganguly describes a low dosage form for delivery to a patient, the contemplation is clearly that the low dosage form a merely 1 of a multi-delivery system. Clearly this does not suggest or describe a low dosage, sustained release form where the complete daily dosage is administered as a single unit. For these reasons, applicant would urge that the invention is not merely optimization of the dosage form described by Ganguly. If one were to try and optimize the dosage forms of Ganguly, one would not be led to a single daily dosage form having a low dosage level in sustained release form. One would be led to select an amount of ribavirin and then determine whether it is to be administered over the day in 2, 4

or even 6 unit dosages.

Clearly, the teaching of Ganguly standing alone does not lead one skilled in this art to the specific invention presently claimed.

As applicant has noted previously, Ganguly does not disclose or suggest the benefit to be derived from the use of the present invention, i.e. selective antiviral effect in the liver and reduced side effects through out the rest of the systemic system.

Applicant would, also, note that the dosage ranges suggested by Ganguly bare no relationship to the actual practice in the field of medicine. Applicant includes with this response, two portions of articles which are representative of the state of the art both prior to the date of invention (Jen et al., Clin. Pharmcol. Ther., 2002 Oct; 72(4): 349-361 and as recent as the end of 2008 (Zopf et al., Scand. J. Gastroenterol, 2008 Dec 31: 1-5. Both make clear that, in the treatment of viral infections with interferon/ribavirin, the acceptable daily dosage rate for the ribavirin component is between 800 to 1200 mg/day. This merely demonstrates that the low dosages described by Ganguly are intended to be single dosages in a multi dosage daily treatment. There is no suggestion that a single sustained release dosage would be effective or even useful.

For these reasons, applicant request reconsideration of withdrawal of the present rejection under 35 U.S.C. 103 (a).

Rejection of claims 5, 6, and 36:

At page 7 of the most recent Office action the Examiner has maintained

the rejection claims 5, 6, and 36 under 35 U.S.C. 103(a) as unpatentable over Ganguly and Wong et al. (612803).

It would appear that Wong et al is cited to provide the materials and forms for a sustained release dosage form of a drug. It is noted that Wong does not indicate that the sustained release forms described might be useful for ribavirin. Thus, the combination is only supported by the limited mention in Ganguly that ribavirin can be used in sustained release form. What is missing, is anything that would have directed one or ordinary skill in this art to a single dose, low dosage sustained release form of ribavirin. As discussed, above, the disclosure of Ganguly is silent on both the actual form and dosage level of a sustained release form of ribavirin and fails to recognize the benefits to be derived from such a formulation. Thus, if the teachings of Wong and Ganguly are combined, one skilled in the art is still left to experiment and without particular direction to try and arrive at the claimed invention. The Examiner arguments regarding optimization fail here as above. Clearly a dosage level of 1000 mg/day, for an appropriate time period, of ribavirin would likely be effective in treating viral infection in a patient. There is nothing that would have led one skilled in the art to have selected from the very broad ranges of Ganguly, a particular dosage level to incorporate into the sustained release forms described by Wong. Since the sustained release dosage form is intended to replace a multi-dose regimen, it would be expected that one skilled in the art would have been led, not to the lower dosages of the present invention, but to the high dosage levels needed for effective treatment. There is nothing in either reference which would have

suggested that one could use a lower dose level rather than a higher dose level because the delivery form is a sustained release form.

For these reasons, and those set forth above that specifically discuss the deficiencies of Ganguly, applicant would request reconsideration and withdrawal of this rejection of claims 5, 6, and 36.

Rejection of claims 29-31:

At page 8 of the most recent Office action, the Examiner has maintained the rejection of claims 29-31 as being unpatentable over Ganguly and Wong, taken in further view of Brass (6849524).

It would appear that the Examiner has relied upon Brass for the suggestion to incorporate antioxidants, such as vitamin E and vitamin C into the formulation that the Examiner urges is suggested by the combination of Ganguly and Wong.

Applicant would note that since this rejection relies primarily on Ganguly and/or the combination of Ganguly and Wong that it is flawed for the reasons set forth above where applicant has addressed the rejections based on these references. Brass adds nothing, other than the specified antioxidants, that would cure the deficiencies of Ganguly and/or Wong. Therefore, applicant would urge that this ground of rejection should fail for the same reasons. Applicant requests reconsideration and withdrawal of this ground of rejection.

Rejection of Claim 23, based on potential double patenting:

In an effort to reduce prosecution efforts, applicant has canceled claim 23 without prejudice to the subject matter therein. This is believed sufficient to avoid

this ground of rejection.

Conclusion:

In conclusion, applicant has presented amendments to the claims which are urged to be sufficient to overcome or avoid each of the objections and rejections set forth in the Office action of October 22, 2008. Applicant, respectfully, requests that the Examiner reconsider these rejections and find all claims allowable.

Applicant respectfully requests favorable consideration of the present application and a timely examination of the pending claims.

Should any official at the United States Patent and Trademark Office deem that any further action by the Applicant or Applicant's undersigned representative is desirable and/or necessary, the official is invited to telephone the undersigned at the number set forth below.

The Commissioner is herby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17 or credit any overpayment, to deposit account No. 503321. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, or otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 503321.

Respectfully submitted,

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